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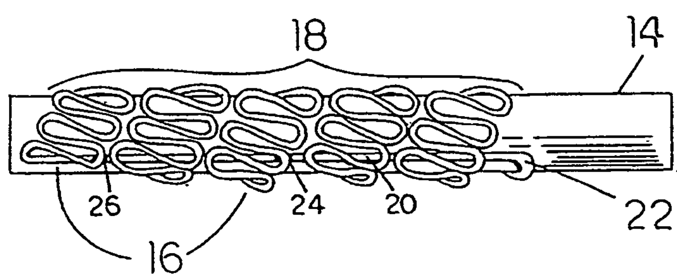

(57) Abstract

An improved radially expandable stent formed from a fine wire bent into a serpentine flat ribbon which is wound around a mandrel (14) into a cylindrical sleeve for mounting on a balloon catheter for transluminal insertion in a vessel such as a blood vessel is provided. A very small diameter fine platinum wire is used to form the basic cylindrical sleeve and it is welded (22), (24), (26) to a pigtail (20) of the wire forming the sleeve to provide longitudinal stability.

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INTRAVASCULAR RADIALLY EXPANDABLE STENT AND METHOD

Field of the Invention:

This invention relates to intravascular implants for maintaining vascular patency in human blood vessels. More particularly, this invention relates to a radially expandable stent made from a fine wire formed into a serpentine ribbon wound into a cylindrical shape for introduction into a body vessel for balloon expansion therein in a radial fashion to support the wall of the vessel when in the expanded configuration. This invention is particularly useful in transluminar implantation of a stent for use in the coronary angioplasty to prevent restenosis.

Background of the Invention:

The basic concept of stents has been known for a number of years. Various types of stents have been proposed and patented, including self-expanding spring types, compressed spring types, mechanically actuated expandable devices, heat actuated expandable devices, and the like. More recently, expandable sleeves have been proposed such as shown in U.S. patent No. 4,733,665 to Palmaz, issued March 29, 1988. In this and other patents Dr. Palmaz suggested a series of metal sleeves which could be expanded by a balloon catheter through the elastic limit of the metal so as to permanently deform them into contact and support of the interior surface of the blood vessel in question. Subsequently, patents to Hillstead, Pat. No. 4,865,516 issued August 16, 1989 and patent No. 4,886,062 issued December 12, 1989 to Wiktor, have shown stents formed of a zigzag wire wound around a mandrel in a somewhat cylindrical fashion which can then be mounted on a collapsed catheter balloon and expanded after introduction into the vessel by expanding the balloon catheter. These prior art devices have been satisfactory for certain installations, but have been limited in the amount of support that can be provided to the interior of the blood vessel wall and in some cases, to the ratio of

expansion possible, and in others cases in the size of the profile presented for the transluminal insertion.

Objects and Summary of the Invention

Accordingly, it is an object of the present invention to provide a stent that overcomes the limitations of the prior art.

It is another object of the present invention to provide a radially expandable stent that can be formed from very fine wire to present a very low profile for introduction into a blood vessel.

It is a further object of the present invention to provide a fine wire stent that is economical to produce and yet able to maintain the desired shape and size in the expanded state after installation.

It is yet a further object of the present invention to provide a radially expandable stent that is longitudinally dimensionally stable.

It is still a further object of the present invention to provide a radially expandable stent with sufficient surface area to fully support the interior walls of a body vessel when inserted therein.

These and other objects of the present invention are accomplished in one embodiment formed from a fine wire bent into a flat serpentine ribbon and wound around a cylindrical mandrel to form a cylindrical sleeve for application to a collapsed balloon catheter for transluminal insertion in a blood vessel and later expansion by inflation of the balloon catheter at the desired site.

Brief Description of the Drawings:

These and other and further objects of the present invention with additional features and advantages accruing therefrom will be apparent from the following description shown in the accompanying drawings wherein:

Fig. 1 is an enlarged scale plan view of the first step of the formation of a fine wire into the ribbon of the present invention;

Fig. 2 is a view similar to Fig. 1 of the serpentine wire ribbon formed from the wire configuration of Fig. 1;

Fig. 3 is a view of the wire ribbon of Fig. 2 wound about a mandrel to form a helix; with the wire pigtail of the ribbon of Fig. 2 welded to the helix;

Fig. 4 is a view similar to Fig. 3 showing the stent mounted about a collapsed balloon catheter inserted in a blood vessel; and

Fig. 5 is a view similar to Fig. 4 on a reduced scale showing the expanded stent in position in a blood vessel for holding the blood vessel in the open configuration.

Detailed Description of the Preferred Embodiment:

Referring now to Fig. 1, a stent in accordance with the present invention is formed by first taking a fine wire 10 having a diameter of approximately .004", preferably made from platinum and forming it into a generally sinusoidal form, as shown in Fig. 1 in which approximately ten cycles or segments per inch are formed in the wire. These bends can be formed in any convenient manner, for instance as by bending about a rack gear by running a corresponding spur gear over a wire laid along the rack.

As may be seen in Fig. 2, the next step is to take the wire of Fig. 1 and to further bend it into a serpentine or figure eight configuration so that the edges of each eight touch and abut the adjacent edges of the next figure eight forming the tight-looped serpentine ribbon form 12 shown in Fig. 2. In this configuration, approximately forty loops 13 per inch of ribbon are present and the height or "amplitude" of the loops is approximately 1/16". This is accomplished by mechanically bending the partially formed loops of Fig. 1 up against each other into the shape shown in Fig. 2.

The fine wire 10 used to form the basic flat ribbon 12 is a soft platinum wire that has been fully

annealed to remove as much spring memory as possible. The straight wire before bending, being in the fully annealed condition, will retain whatever shape it is formed into.

After the flat narrow serpentine ribbon 12 is formed, as shown in Fig. 2, the ribbon 12 is wrapped about a mandrel 14 having a diameter of .060" in a spiral or helix fashion with the edges of each helix wrap 16 of the ribbon 12 basically touching the adjacent ribbon helix edges to form a wire sleeve 18. The number of convolutions or helix 16 on the mandrel will determine the length of the sleeve 18, and a typical stent of this type may have a length of approximately one and one-half inches.

According to the present invention, as the serpentine ribbon 12 of Fig. 2 is wound on the mandrel 14 of Fig. 3 the pigtail 20 of the wire of Fig. 1 is inserted through the helix, as may be seen in Fig. 3. In actual practice, the ribbon 12 is wound about the mandrel 14 over top of the pigtail 20 of the wire 10. After the helix is formed to the desired length, the free end of the pigtail 20 extending through the helix is trimmed and welded smoothly to the final turn of the helix 16 so as not to present any increased profile and so as not to puncture or pierce the balloon catheter or the blood vessel into which it is being inserted. The end turn of the helix is welded at 22 and intermediate welds such as 24 are formed to stabilize the length of the helix. The first turn of the helix at the other end may also be welded to the pigtail at 26 so that the overall length of the stent can be constrained and maintained in the desired configuration.

The serpentine ribbon sleeve 18 is next placed about a collapsed balloon catheter as shown in Fig. 4. In this configuration, the sleeve 18 generally has a diameter in the neighborhood of 1.5 mm for insertion into the blood vessels adjacent the heart.

In use, the stent is mounted on a balloon catheter as shown in Fig. 4 and is inserted into the appropriate

blood vessel. The stent is guided to the desired location where there is occluding plaque 28 or a weak vessel wall or other imperfection requiring placement of a stent. Once the stent is properly located and verified by fluoroscopic or other means, the balloon catheter is inflated to radially expand the serpentine wire sleeve 18. As the balloon expands, it expands the tight figure 8 bends of the serpentine ribbon 12 from "touching adjacent loops" shown in Figs. 2-4 to a spaced apart condition as shown in Fig. 5. For instance, in a particular embodiment where the diameter of the stent on the collapsed balloon catheter was 1.5 mm, the stent has been expanded to 4 mm to 5 mm within the blood vessel. The space 30 between adjacent loops then increases to something approximating .0875" with the loop dimension being approximately .025". Thus, what initially in Fig. 2 was a "wavelength" of .025", now becomes a "wavelength" of .1125". This is an increase of 4.5 times and is perhaps one of the more common expansion ratios found with stents of this type. With the present stent expansion of up to 8 mm or six times has been found to be entirely satisfactory.

At the same time, the "amplitude" or width 34 of the ribbon 12 decreases some 20% to 25% due to the lengthening of the helix wrap due to the increased circumference of the expanded sleeve. Thus, as the helix 16 is lengthened by stretching the helix about the increased circumference of the expanded stent, the adjacent loops 13 are separated by spaces 30 at the same time the amplitude 34 of the individual helixes decrease. Also, the overall length of the sleeve 8 tends to decrease even to the point of causing the pigtail 20 to bend between the welds 22, 24 and 26. The pigtail 20 prevents extension of the overall length of the sleeve 18, but allows it to contract as the diameter increases. The length tends to decrease because the middle of the balloon, and hence the middle of the stent, expands the most, pulling the ends toward the center.

It will be seen that this action maintains good interior surface support of the blood vessel by maintaining the close spacing of the wire loops and helixes forming the sleeve.

The expanded condition of the stent is shown in Fig. 5 with the balloon catheter having been removed and the back portion of the sleeve 18 shown in dotted lines for clarity of presentation. Even in this expanded configuration, however, it will be seen that there are ample turns of wire spaced closely enough to fully support the inner surface of the blood vessel so as to prevent collapse of the plaque occluded vessel. With this finer "mesh" serpentine configuration, smaller diameter wire can be used without losing the necessary support for the interior surface of the blood vessel, and thus the stent presents a lower profile during introduction which increases the utility of the stent for smaller blood vessel usage. This "finer mesh" also results in a more flexible sleeve which, together with the smooth uniform surface of the tightly wound serpentine wire ribbon of Figs. 2 and 3, improves the ease of transluminal insertion and facilitates proper implantation and location of the stent. Since the wire pigtail has no sharp ends and the free end is welded to the loop of the helix, there are no sharp edges or points to tear or catch on the catheter balloon or the interior surface of the blood vessel, and thus the stent of the present invention can be more readily manipulated to the desired location.

In prior art devices where the necessary surface support had to be achieved by heavier wire or a denser sleeve, it became difficult to flex the sleeve so as to transit the convoluted blood vessels. When a looser wire configuration was employed, the stability of the stent was decreased and the ultimate efficacy of the implanted stent compromised.

Since the stent of the present invention is welded to the longitudinal wire at several locations, the

longitudinal stability of the stent is greatly increased over the prior art devices without creating a stiff and inflexible stent that cannot be manipulated around curves and corners of the vessel into which it is to be introduced.

In some prior art applications, sleeves of platinum were objectionable because of its inherent high elastic limit such that it required extreme pressures to expand and to hold it in the expanded configuration without contraction sometimes causing insufficient support of the wall surfaces. With the serpentine construction of the present wire form, the elastic limit of in the annealed platinum wire can easily be overcome and the device can be fully expanded radially to support the blood vessel with very little pressure required from the balloon catheter. Thus, applicant is able to provide a stent which is more radiopaque than, for instance, stainless steel, without encountering the usual modulus of elasticity problems with platinum. This allows good visibility during implantation and speeds the procedure of positioning the stent in the proper location within the vessel.

Thus with the construction and configuration shown, I have provided a stent having good flexibility, dimensional stability, minimal impurities, very smooth surface, low profile and immunity to fatigue and corrosion.

While this invention has been explained with reference to the structure disclosed herein, it is not confined to the details as set forth and this application is intended to cover any modifications and changes as may come within the scope of the following claims. following claims.

What is Claimed is:

1. A radially expandable stent for transluminal implantation including a continual length of wire formed into a flat serpentine ribbon containing alternately inverted oval shaped loops, each loop being of a uniform size and shape and having a pinched opening at one end thereof lying along one edge of the ribbon and a laterally disposed bottom wall at the other end thereof lying along an opposing edge of said ribbon, said ribbon being further wound into a tight spiral sleeve with said top and bottom edges of the ribbon being in close relation to each other, and retaining means joined to said sleeve to prevent axial movement of the sleeve when the sleeve is expanded radially.

2. The radially expandable stent of claim 15 wherein the retaining means is a linear section of wire that is integral with said ribbon.

3. The radially expandable stent of claim 16 wherein said linear section of wire is integrated with the last loop in said ribbon and is passed back axially along said sleeve.

4. The radially expandable stent of claim 17 that further includes weld means for joining said linear section of wire to the sleeve.

5. The radially expandable stent of claim 15 wherein said wire is annealed prior to forming said ribbon.

6. The radially expandable stent of claim 15 wherein the edges of said sleeve are in contact with each other.

7. The radially expandable stent of claim 15 wherein said wire is formed of annealed platinum.

8. The radially expandable stent of claim 21 wherein said wire has a diameter of about 0.004 inches and the ribbon is about 1/16 of an inch wide over said opposed edges.

9. A method of forming a radially expandable stent for transluminal implantation comprising the steps of

forming a continuous length of fine wire into a flat rectangular shaped ribbon containing alternately inverted oval shaped loops with each loop having an opening situated at one edge of the ribbon and an expanded base lying along an opposed edge of said ribbon;

closing the opening of each loop; and

winding the ribbon into a tight spiral sleeve with the edges of the ribbon being in close relation to each other.

10. The method of claim 23 that further includes the step of pre-forming said wire into a sinusoidal-shape having a series of waves, each half wave of the sinusoid being triangular shaped and having a flat planar surface at its apex and an open base section.

11. The method of claim 23 that further includes the step of joining an axially disposed wire section to the sleeve to prevent the sleeve from expanding axially.

12. The method of claim 25 including the further step of forming said axially disposed wire section as an integral part of the last loop in said ribbon.

13. The method of claim 26 that includes the further step of welding said wire section to said spiral sleeve.

14. The method of claim 23 that further includes the step of annealing the wire prior to forming.

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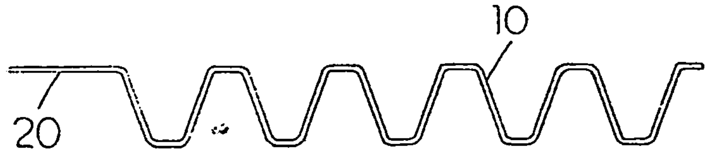

FIG. 1

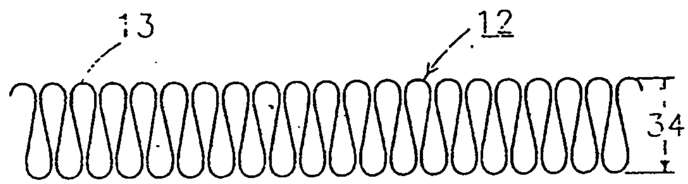

FIG. 2

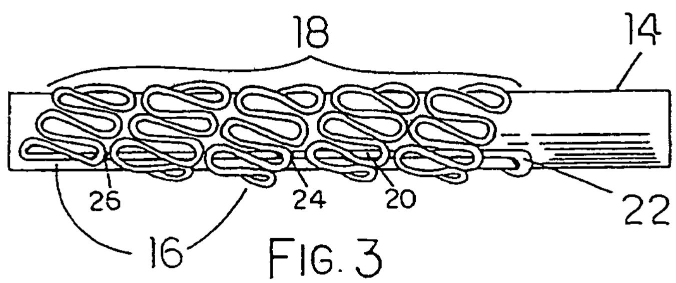

FIG. 3

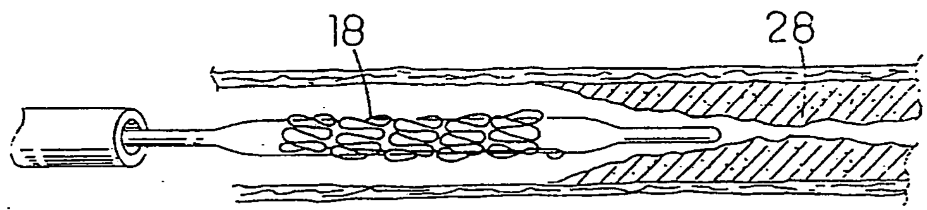

FIG. 4

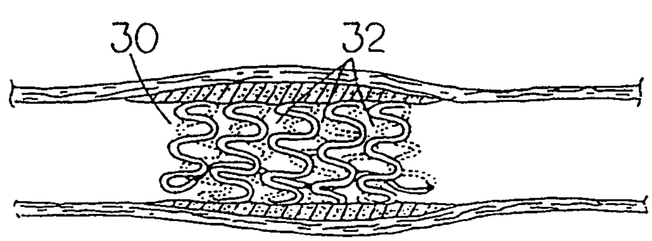

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/08916

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/06

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
A	EP,A,0 357 003 (CORVITA CORP) 7 March 1990 see claims 1,15; figures ---	1,9
A	EP,A,0 282 175 (COOK INC.) 14 September 1988 ---	-

° Special categories of cited documents : [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13 APRIL 1992	20. 05. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	VILLENEUVE J.M.

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9108916 SA 55968

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 13/04/92
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0357003	07-03-90	US-A- 5019090	28-05-91
		JP-A- 2068052	07-03-90
EP-A-0282175	14-09-88	US-A- 4800882	31-01-89
		AU-B- 593721	15-02-90
		AU-A- 1278288	15-09-88
		DE-A- 3866380	09-01-92
		JP-A- 63230158	26-09-88
		US-A- 4907336	13-03-90
		US-A- 5041126	20-08-91

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